

REMARKS

Applicant has carefully reviewed the Final Office Action mailed February 3, 2009, prior to preparing this response. Currently claims 1-13 and 19-26 are pending in the application, wherein claims 1-4, 7-13, 19-21 and 24-26 have been rejected and claims 5-6 and 22-23 have been withdrawn consequent an Examiner-induced restriction requirement. Favorable consideration of the following remarks is respectfully requested.

Claim Rejections under 35 U.S.C. § 102

Claims 1, 7-13 and 26 stand rejected under 35 U.S.C. §102(b) as being anticipated by Roll (U.S. Patent No. 5,419,764). Applicant respectfully traverses this rejection.

Independent claims 1 and 26 each recite the limitation “an interference fit member including a second material disposed about at least a part of the portion of the hub assembly including the first material.” Applicant asserts Roll fails to teach at least this limitation of the claims including the stated arrangement of the claimed elements.

In Applicant’s previous response it was pointed out that Roll discloses an O-ring 105 disposed about shaft 113 (see column 3, lines 51-52), between members 104 and 106. In formulating the rejection, it appears as though the Examiner is relying on feature 113 of Roll as teaching the claimed elongate shaft and feature 104 of Roll as teaching the claimed hub assembly. See Final Office Action, February 3, 2009, at paragraph 3. Thus, the shaft 113 is the feature of Roll, relied on in formulating the rejection, as being equated to the claimed elongate shaft, not the hub assembly. However, in responding to Applicant’s previously presented arguments in which Applicant respectfully disagreed with the Examiner’s assertion that the O-ring is disposed about member 104 (which the Examiner asserts a being “the hub assembly”), the Examiner now states that “the shaft (113) is directly attached to the hub assembly (104); hence, it can be said that the shaft is a part of the hub assembly.” Final Office Action, February 3, 2009, at paragraph 6.

Applicant respectfully disagrees with the Examiner’s positions. The Examiner is presenting two conflicting and contradicting characterizations of Roll. Namely, in formulating the rejection at paragraph 3 the Examiner presents a first characterization of Roll in which the Examiner relies on feature 113 of Roll as teaching the claimed elongate shaft connected to the hub assembly. However, at paragraph 6, the Examiner presents a second characterization of Roll

in which the Examiner relies on feature 113 of Roll as a portion of the hub assembly. Applicant asserts that neither of these two characterizations of Roll teaches each element of claim 1, and it would be improper to take portions of the first characterization and combine them with portions of the second characterization as the Examiner is suggesting.

In the event the Examiner adheres to the first characterization of Roll in which the Examiner relies on feature 113 of Roll as teaching the claimed elongate shaft and feature 104 as teaching the claimed hub assembly, then as pointed out in Applicant's previous remarks, the O-ring is not disposed about the hub assembly (feature 104), but rather is disposed about the elongate shaft (feature 113). This characterization of Roll does not meet the claim limitations of claim 1.

In the event the Examiner adheres to the second characterization of Roll in which the Examiner relies on feature 113 of Roll as a portion of the claimed hub assembly, then Applicant respectfully points out that no feature of Roll would meet the claimed element of an elongate shaft disposed within the lumen of the generally tubular member.

Applicant respectfully asserts that it would be impermissible to suggest that feature 113 meets one claimed element (i.e., the elongate shaft connected to the hub assembly), and then suggest that that same feature is a portion of the hub assembly. Either feature 113 of Roll should be relied on as an elongate shaft (the first characterization) or feature 113 should be relied on as a portion of a hub assembly (the second characterization). It is noted that in order to anticipate "[t]he identical invention must be shown in as complete detail as is contained in the ...claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1990).

For at least these reasons, Roll does not anticipate either claim 1 or claim 26. Claims 7-13, which depend from claim 1 and include additional limitations, are also believed patentable over Roll. Withdrawal of the rejection is respectfully requested.

Claim Rejections under 35 U.S.C. § 103

Claims 1-4, 7-11, 13, 19-21 and 24-26 stand rejected under 35 U.S.C. §103(a) as being unpatentable over McGlinch et al. (U.S. Patent No. 7,214,220), in view of Gadberry et al. (U.S. Patent No. 5,217,114). Applicant respectfully traverses this rejection, asserting a *prima facie* case of obviousness has not been established.

The Examiner admits that McGlinch et al. do not provide all elements of independent claims 1, 19, and 26. However, in formulating the rejection, the Examiner states that "it would have been obvious...to have substituted the IFM (65) including a second material of Gadberry for the IFM (40) of McGlinch in order to create an air tight seal when enclosing the elongate medical device as taught by Gadberry." Final Office Action, February 3, 2009, at paragraph 4.

Applicant respectfully disagrees with this suggestion proposed by the Examiner, asserting that the Examiner's suggestion cannot be attained without following an impermissible hindsight analysis. The Federal Circuit has recently reaffirmed that a flexible application of a Teaching, Suggestion, Motivation (TSM) Test is an effective means to prevent hindsight and focuses on evidence before the time of invention. The Federal Circuit stated "As this court has explained, however, a flexible TSM test remains the primary guarantor against a nonstatutory hindsight analysis." *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc.*, 520 F.3d 1358, 86 USPQ2d 1196 (Fed. Cir. 2008).

Applicant respectfully asserts that there is no rationale for combining the O-ring 65 disclosed in Gadberry et al. on the hub assembly of the catheter of McGlinch et al. to provide an air tight seal between the hub assembly of the catheter and the packaging tube. McGlinch et al. disclose a hub assembly including an interference fit member (IFM) 40. McGlinch et al., at column 3, lines 44-46. McGlinch et al. disclose that the catheter may be disposed in a carrier tube 10 such that "[t]he interference fit between the IFM 40 and the carrier tube 10 establishes sufficient friction to resist gravitational and handling forces which may otherwise cause the device 20 to fall out of the carrier tube 10. Thus, McGlinch et al. expressly indicate to one of skill in the art that the interference fit member is provided to create an interference fit between the hub assembly and the carrier tube. At no point do McGlinch et al. suggest the need or desire to create an air tight seal between the hub assembly of the catheter and the carrier tube. For instance, as shown in FIG. 1, the distal end of the carrier tube 10 may be open to the interior of the carrier tube 10, thus providing an air tight seal between the hub assembly and the carrier tube 10 would be pointless as the distal end of the carrier tube 10 would remain open to the interior of the carrier tube. Furthermore, several of the configurations of an interference member disclosed in McGlinch et al. only contact the inner surface of the carrier tube at discrete points, less than the entire circumference of the inner surface of the carrier tube. See, for example, FIGS. 4, 6 and 11.

Furthermore, Gadberry et al. do not motivate one of skill in the art to provide an air tight seal between a hub assembly of a catheter and a packaging tube. Rather, the O-ring is located at an interface between the cap 27 and the tube 23 of the catheter package 10. The O-ring disclosed in Gadberry et al. is not a part of the catheter 12 at all. At no point do Gadberry et al. suggest the desire to form an air tight seal between the hub 16 of the catheter 12 and the catheter packaging 10.

Applicant submits that the difference between the devices of McGlinch et al. and Gadberry et al. discussed herein indicate that a person of ordinary skill in the art would not be inclined to combine McGlinch et al. with Gadberry et al. as proposed in formulating the rejection. Namely, there is no rationale to provide an air tight seal between the hub assembly of the catheter and the packaging tube, as suggested in formulating the rejection. Applicant asserts that it is only by applying impermissible hindsight using the instant application as a roadmap would the hub assembly of McGlinch et al. be modified by the O-ring of Gadberry et al. as asserted in the Office Action (See for example, *Ruiz v. A.B. Chance Co.*, 69 USPQ2d 1686, 1690 (Fed. Cir. 2004): The “as a whole” instruction in Title 35 prevents evaluation of the invention part by part. Without this important requirement, an obviousness assessment might break an invention into its component parts (A + B + C), then find a prior art reference containing A, another containing B, and another containing C, and on that basis alone declare the invention obvious. This form of hindsight reasoning, using the invention as a roadmap to find its prior art components, would discount the value of combining various existing features or principles in a new way to achieve a new result – often the very definition of invention).

To ensure that the invention is considered “as a whole” the Federal Circuit requires “a showing that an artisan of ordinary skill in the art at the time of invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would select the various elements from the prior art and combine them in the claimed manner. In other words, the examiner or court must show some suggestion or motivation, before the invention itself, to make the new combination” (*Ruiz v. A.B. Chance Co.*, 69 USPQ2d 1686, 1690 (Fed. Cir. 2004 citing *In re Rouffet*, 149 F.3d 1350, 1355-56 [47 USPQ2d 1453] (Fed. Cir. 1998); emphasis added). The Federal Circuit has made it clear that this showing of motivation to combine two or more references must be “clear and particular” (See for example, *Winner International Royalty*

Corp. v. Wang, 53 USPQ2d 1580, 202 F.3d 1340 (Fed. Cir. 2000)). No such showing has been established with the cited combination of references.

For at least the reasons stated above, Applicant believes that a *prima facie* case of obviousness has not been established with the cited combination. Withdrawal of the rejection of claims 1-4, 7-11, 13, 19-21 and 24-26 under §103(a) is respectfully requested.

Claim 12 stands rejected under 35 U.S.C. §103(a) as being unpatentable over McGlinch et al. (U.S. Patent No. 7,214,220), and Gadberry et al. (U.S. Patent No. 5,217,114), in view of Roll (U.S. Patent No. 5,419,764). Applicant respectfully traverses this rejection, asserting a *prima facie* case of obviousness has not been established.

Claim 12 depends from independent claim 1. For at least the reasons stated above regarding the allowability of claim 1, Applicant submits that claim 12 is also allowable. Withdrawal of the rejection is respectfully requested.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By his Attorney



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3/25/09